

## **REMARKS**

The Final Office Action mailed January 29, 2004, has been received and carefully considered. Upon the grant of Applicants' Request for Continued Examination and entry of the preceding amendments, claims 1, 2, 5, 7-40, and 42-47 will be pending, of which claims 13-40, and 42-43 remain withdrawn. Claims 1, 2, 5, 7-12 and 44-47 stand rejected. Claims 12, 44, 46 and 47 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the invention. Claims 1, 2, 5, 7-12, and 44-46 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent 5,658,329 to Purkait ("Purkait") in view of WO 99/10021 to Topalov, et al. ("Topalov") and WO 01/49336 to Lopatine et al. ("Lopatine"). Claim 47 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Purkait as modified by Topalov and Lopatine in further view of U.S. Patent 5,700,289 to Breitbart (Breitbart).

### **I. Amendments to Claims.**

Claims 1, 12, 44 and 46 are amended. Support for the claim amendments is found throughout the specification as filed and no new matter is presented.

### **II. Rejection under 35 U.S.C. § 112.**

Claims 12, 44, 46 and 47 stand rejected under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that the claims prior to their amendment herein were definite because they readily appraised persons skilled in the art of the metes and bounds of the claimed invention. In the interest of expediting prosecution, Applicants amended these claims. Applicants submit the claims as amended address the Examiner's concerns with respect to claims 12, 44, and 46 and continue to be definite. With respect to claim 47, Applicants traverse the Examiner's rejection. Although the preamble recites a hydrogel, there is nothing in this preamble that precludes the hydrogel from further comprising cells that facilitate cellular engraftment. Therefore, Applicants respectfully request the withdrawal of the rejection of claims 12, 44, 46 and 47 under 35 U.S.C. § 112, second paragraph.

### **III. Rejection under 35 U.S.C. § 103(a).**

Claims 1, 2, 5, 7-12, and 44-46 stand rejected under 35 U.S.C. § 103(a) as obvious over Purkait in view of Topalov and Lopatine. Claim 47, which depends from claim 1, stands rejected further in view of Breitbart. Applicants respectfully traverse these rejections.

As discussed in Applicants' response of November 5, 2003, Lopatine is not prior art under 35 U.S.C. § 102(e). The Application claims priority from U.S. Provisional Application No. 60/228,081, filed August 25, 2000. Revised Section 102(e) applies to PCT applications filed on or after November, 29, 2000. Lopatine was filed December 29, 1999, therefore Lopatine is not prior art under 35 U.S.C. § 102(e). Because Lopatine did not publish until July 21, 2001, it is also not prior art under any other section of 35 U.S.C. § 102. Although the Examiner has withdrawn the previous rejection under 35 U.S.C. § 102(e), the Examiner has not stated how Lopatine is still prior art with respect to the Application such that it may be used in making a rejection under 35 U.S.C. § 103(a). Lopatine is cited against Applicants' claimed invention for its disclosure of monomer concentration. *See* Office Action at pg. 3. 35 U.S.C. § 103(a) clearly requires that references used to reject the claims under this section must be prior art. *See also* MPEP § 2141.01. For at least this reason, withdrawal of all rejections based on Lopatine is respectfully requested.

Furthermore, a proper obviousness analysis under § 103(a) requires consideration of: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicants' disclosure. *Id* at 493. *See also* MPEP § 2142.

Purkait discloses a hydrogel containing 2-20% polyacrylamide in pyrogen-free water. The viscosity range disclosed by Purkait is 15 to 75 Pa·s. *See* Purkait, col. 3, lines 50-55. Topalov and Lopatine are cited for their disclosure of methylene bis-acrylamide as a cross-linking agent. *See* Office Action at pg. 3. Lopatine is further cited for its disclosure of monomer

less than 50 ppm, but for the reasons set forth above, Lopatine cannot be relied upon to reject Applicants' claims.

The hydrogel disclosed by Purkait is specifically intended for use only as a filling material in a prosthesis that includes a shell to contain the filling material. *See* Purkait, col. 2, lines 46-49. Purkait is not directed to a bio-stable hydrogel which is itself used as an endoprosthesis, as in Applicants' claimed invention.

The filling material according to Purkait "must necessarily be compatible with the shell material in that it cannot react with the shell, and the shell must be capable of retaining the filling material without substantial leaking or bleeding." *See* Purkait, col. 3, lines 62-66. Thus, Purkait fails to disclose or suggest a bio-stable hydrogel which is compatible with surrounding tissues and does not teach, disclose or suggest a hydrogel composition for use alone as an endoprosthesis. As the hydrogel composition of Purkait is not bio-stable for use in the body, its composition must be different from Applicants' claimed hydrogel composition, although this does not preclude Applicants' claimed hydrogel from first being contained by an envelope, as in claim 46.

In the event that the filling material according to Purkait does leak, the filling material should be "biocompatible, including non-toxic, and relatively easily excreted or metabolized." *See* Purkait, col. 3, lines 6-8. Again, at least one difference between the composition of Purkait's filling material and Applicants' claimed invention is apparent. Any contact with the tissue by the filling material of Purkait is clearly accidental and the filling material is subsequently eliminated from the body by excretion or metabolism. Applicants' claimed composition is bio-stable; were it easily excreted or metabolized as is the filling material of Purkait, Applicants' claimed hydrogel could not itself be an endoprosthesis as it would simply disintegrate.

A person ordinarily skilled in the art who develops a filling material to be contained within a shell would not have the same motivations as a person developing a bio-stable hydrogel that is itself used as an endoprosthesis. A material which is in direct contact with body tissue presents a host of considerations, including various desirable physical properties and biocompatibility aspects, which would not be considered by one developing a filling material that is only contained within a shell and is not in direct contact with tissue.

For example, Purkait does not teach or suggest a bio-stable hydrogel with an elasticity module from about 10 to 700 Pa to be used as an endoprosthesis, nor does Purkait teach or suggest a molar ratio of 150:1 to 1000:1 acrylamide to methylene bis-acrylamide.

Applicants' claimed invention also has a narrower range of the polyacrylamide polymer content: 0.5-3.5% compared to Purkait's 2-20 %. The solid weight content selected for a filling material would not necessarily be the same as and would not necessarily suggest the solid weight content selected for a bio-stable hydrogel used as an endoprosthesis, as claimed by Applicants.

Thus Purkait does not teach, disclose, or suggest the limitations found in Applicants' claimed invention. As Topalov does not supply these deficiencies, the prior art does not teach, disclose, or suggest every limitation of Applicants' claimed invention and the rejection must be withdrawn.

As claim 47, rejected in further view of Breitbart, is dependent from claim 1, which has now been shown as allowable, this rejection should also be withdrawn.

**CONCLUSION**

For at least the reasons stated above, claims 1, 2, 5, 7-12 and 44-47 are in condition for allowance. Accordingly, Applicants respectfully request that upon entry of the preceding amendments the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to Applicants' undersigned representative to resolve such issues in an expeditious manner.

A check in the amount of \$880 is submitted herewith for the Request for Continued Examination and a one month extension of time in which to file this paper. In the event any additional fees are due, the Commissioner is authorized to charge those fees to the undersigned's Deposit Account No. 50-0206.

Date: June 1, 2004

Respectfully submitted,

By:  #50,311

Stanislaus Aksman  
Registration No. 28,562  
Shawn K. Leppo  
Registration No. 50,311  
(804) 788-8516 (direct telephone)

**Please direct all correspondence to:**

Stanislaus Aksman  
**HUNTON & WILLIAMS, LLP**  
1900 K Street, N.W.  
Suite 1200  
Washington, DC 20006-1109  
(202) 955-1926 telephone number  
(202) 778-2201 facsimile number